REMARKS

The applicants appreciate the Examiner's thorough examination of the application and request reexamination and reconsideration of the application in view of the preceding amendments and the following remarks.

The applicants acknowledge and appreciate the Examiner's allowance of claims 21-34.

THE RESTRICTION/ELECTION

The Examiner states that a complete reply must include cancellation of non-elected claims 12-16, 19, 35-44, 53-57, 60 and 67-97, or other appropriate action.

In response, the applicants have cancelled claims 67-97, which may be the subject of divisional application at some future date.

Claims 35-44 are dependent claims which ultimately depend from independent claim 21, which has been allowed.

Accordingly, the applicants submit that claims 35-44 should not be cancelled, but that other appropriate action should be taken, namely, allowance of dependent claims 35-44.

Similarly, claims 12-16 and 19 are dependent claims which ultimately depend from independent claim 1, and claims 53-57 and 60 are dependent claims which ultimately depend from independent claim 45.

The applicants therefore respectfully submit that to cancel claims 12-16, 19, 53-57 and 60 would be premature since the applicants are still arguing the patentability of independent claims 1 and 45. If the applicants are successful and claims 1 and 45 are allowed, then these enumerated claims would be allowable as well.

Accordingly, the applicants submit that other appropriate action should be taken with respect to claims 12-16, 19, 53-57 and 60, namely, due consideration of these claims together with independent claims 1 and 45, prior to cancellation of such claims.

THE OBJECTION TO CLAIM 45

The Examiner objects to claim 45 because of an informality. In response the applicants have amended claim 45.

THE REJECTIONS BASED ON *GUISET*

The Examiner rejects claims 1-3, 7-10, 17, 18, 20, 45-47, 49-51, 58, 59, 61, 64 and 65 under 35 U.S.C. §102(b) as being anticipated by U.S. Pat. No. 4,044,401 to *Guiset*. The Examiner also rejects claims 4, 48, and 62 under 35 U.S.C. §103(a) as being unpatentable over *Guiset*.

The applicants recognized the connection between acute renal failure (ARF) and ischemia of the kidney – when oxygen demand by the kidney exceeds available oxygen supply. Known methods for attempting to avert ARF typically include increasing blood flow (and hence oxygen) to the kidney, or after-the-fact supportive treatment of ARF which may include dialysis. See e.g. applicants' specification at page 4, lines 8-13 and page 5, lines 18-21.

The applicants also recognized that if the ratio of renal blood flow (RBF) (determinant of oxygen supply) to the glomerular filtration rate (GFR) (determinant of oxygen demand) is increased, hypoxia or ischemia of the kidney, and resulting ARF, can be averted. See e.g. applicants' specification at page 8, lines 12-15. Also, improved oxygen balance could be

achieved by temporarily reducing kidney demand for oxygen (rather than e.g. increasing blood supply to match increased oxygen demands). See e.g. applicants' specification at page 11, lines 9-15.

The applicants further recognized that one way to effect an increase in the ratio of oxygen supply to oxygen demand, as well as increase the RBF to GFR ratio, is by increasing renal pelvis pressure in a kidney, the renal pelvis defined as a cavity in the middle of the kidney. See e.g. applicants' specification at page 16, lines 1-5; page 13, lines 15-16; page 21, line 15 and element 201, Fig. 2; see also page 18, lines 8-11.

These concepts and more (including common causes for common conditions) are more fully set forth in the applicants' specification.

In summary, in accordance with one embodiment of the subject invention, the applicants have disclosed prevention of ischemia and ARF by increasing renal pelvis pressure in at least one kidney.

For clarification, therefore, applicants have amended claim 1 for clarification, which recites a method to protect a kidney in a mammalian patient comprising: a. artificially increasing renal pelvis pressure including increasing pressure in a urinary tract of at least one kidney of the patient; b. reducing a renal function of the kidney by maintaining the increased pressure, and c. reducing the pressure in the urinary tract to increase the renal function above the reduced renal function.

Independent claim 45 has been amended in similar fashion.

The applicants' invention, as claimed in independent claims 1 and 45, is in sharp contrast to *Guiset*.

Guiset fails to disclose, among other things, that renal pelvis pressure in the kidney is increased. In fact, *Guiset* apparently discloses – perhaps unwittingly – a way to ensure that increased pressure, e.g. renal pelvis pressure, does not occur.

In short, *Guiset* discloses that when the bladder (artificial or impaired) is not full, aperture(s) 3 to ureter(s) 7 are open. Fluid is therefore free to flow from the kidney through aperture(s) 3 into the bladder, and it would follow that no increased renal pelvis pressure would result.

Alternatively, *Guiset* discloses that when the bladder begins to fill near or is at capacity, and balloon 27 in the bladder is filled by squeezing fluid reservoir 23, aperture(s) 3 are closed (by inflating collar 15 with fluid also from reservoir 23). In this latter stage aperture 4 leading to the urethra is deliberately opened (see e.g. *Guiset* column 5, lines 3-30). In such a case, it would follow that bladder pressure and thus pressure upwards toward the kidney would be relieved, even if apertures 3 were open (which they are not, as disclosed by *Guiset*).

Thus, the applicants submit that *Guiset* fails to disclose increasing renal pelvis pressure, at least in part because the aperture(s) 3 leading to the kidney are closed and aperture 4 is open.

It is clear that the structure, function, and principle disclosed by *Guiset* is starkly different than the applicant's claimed invention.

Accordingly, it is clear that *Guiset* fails to anticipate the applicants' independent claims 1 and 45, and the applicants therefore submit that claims 1 and 45 are in condition for allowance. Claims 2-20 ultimately depend from claim 1, and claims 46-61 and 64-66 ultimately depend from claim 45. Accordingly, these dependent claims are in condition for allowance over *Guiset* for at least the same reasons.

THE REJECTIONS BASED ON *CIOANTA ET AL.*

The Examiner rejects claims 1-3, 5, 6-11, 17, 18, 20, 45-52, 58, 59, 61 and 64-65 under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 6,682,555 to *Cioanta et al.*

Particularly, the Examiner points to *Cioanta et al.*'s balloons 15 and 52 as allegedly reducing or inhibiting natural renal function. The Examiner further states that the increased pressure in the anchoring balloon 52 blocks natural urine flow, and that "this limitation is readily [sic] on any pressure being increased within the urinary tract". The Examiner takes this position in spite of the urine drainage port disclosed by *Cioanta et al.* (which specifically allows urine to drain from the bladder).

The applicants respectfully submit that the Examiner's conclusion does not follow from the disclosure of *Cioanta et al.*

The applicant respectfully submits that *Cioanta et al.* fails to disclose that balloon 52 or 15 are meant to or indeed restrict urine flow. In fact, *Cioanta et al.* discloses that these balloons are affixed to and expand from the catheter shaft, and the shaft contains a drainage port therethrough from the bladder to outside of the patient, which purposely and specifically allows for urine flow during treatment. Moreover, *Cioanta et al.* discloses a stent which allows urine flow after the catheter (and balloons) is removed.

Cioanta et al. discloses catheter 20 which is inserted through the penile meatus through the prostate and into the bladder. When in place, catheter 20 thus includes a shaft 21 which extends from inside the bladder to outside of the penile meatus. In the bladder, catheter 20 includes urine discharge port 20e (in Fig 1A, (20a in Fig. 1B)), and *Cioanta et al.* teaches that

"discharge port 20e that is in fluid communication with a urine discharge or drainage channel 52d [outside the penile meatus, see e.g. Fig. 1A] that allows urine to drain from the bladder through the catheter 20 while the catheter is in the subject". See *Cioanta et al.* column 8, lines 23-27 (with emphasis added).

The anchoring balloon 52 is in place to hold the catheter properly so the desired prostate area is ablated. See e.g. *Cioanta et al.* column 1, lines 40-44. The treatment balloon 15 applies the heat for ablation (see e.g. *Cioanta et al.* column 7, lines 59-64), as well as forming the expandable stent which remains after the catheter is removed to allow urine flow, because such procedures tend to cause expansion or swelling which blocks or obstructs the prostatic urethra (see e.g. *Cioanta et al.* column 2, lines 11-17; column 8, lines 30-44; and column 9, lines 8-17).

Cioanta et al. also teaches a sealing balloon 22 which may be placed below the treatment balloon 15 to prevent stent material from flowing to the sphincter 13 (prior to solidification of the stent material), and/or to keep the catheter from moving down when the sphincter opens, or up if the urethral canal opening size is reduced because the treated tissue is swollen, inflamed, or suffering from edema. See e.g. *Cioanta et al.* column 18, lines 49-55 and column 12, lines 16-31.

According to claim 1 of *Cioanta et al.*, a bladder *anchoring balloon* (e.g. 52) "is secured to the shaft ... and configured to expand outwardly from the shaft". A *treatment balloon* (e.g. 15) is "secured to the shaft and configured to expand outwardly therefrom". A *sealing balloon* (e.g. 22) is also "secured to the shaft ... and configured to expand outwardly from the shaft". And importantly, there is "a urinary drainage channel [e.g. 52d] extending through the shaft". See e.g. *Cioanta et al.* claim 1 (with emphasis added) and column 8, lines 22-27.

In other words, as structurally described by *Cioanta et al.*, it is clear that none of *Cioanta et al.*'s balloons interrupt the flow of urine through the urinary drainage channel.

As noted, the treatment catheter is later removed from the subject, leaving the stent in the treatment region. See *Cioanta et al.* column 17, lines 52-54. The stent 75 is "to maintain a desirable opening size in the prostatic urethra lumen when exposed to compressive swelling pressures in the localized treatment region", and "to maintain a sufficiently sized opening in the prostatic urethra treatment region to allow urine drainage during the healing period". See e.g. *Cioanta et al.* column 8, lines 39-61 (with emphasis added).

Thus, according to the teachings of *Cioanta et al.*, urine flow is open at all times during and after treatment. *Cioanta et al.* further teaches that the balloons are attached to and expand from the shaft which includes a channel to allow for urine flow.

In summary, in view of the teachings of *Cioanta et al.*, the applicants submit that *Cioanta et al.* fails to teach that the balloons block urine flow.

Importantly also, the embodiment claimed in applicants' independent claims 1 and 45 includes the recitation of increasing renal pelvis pressure in at least one kidney, among other things, which achieves desirable results as also discussed above and in the applicants' specification.

The applicants respectfully submit that *Cioanta et al.* teaches nothing about increasing renal pelvis pressure at all, in contrast to the applicants' claims 1 and 45. Also, *Cioanta et al.* discloses only a system and method associated with the prostate, not the kidneys.

The applicants' also respectfully submit that *Cioanta et al.* fails to disclose "reducing a renal function of the kidney by maintaining the increased pressure", also in contrast to the applicants' claim 1.

Moreover, it is apparent that the design of *Cioanta et al.*'s entire system is to allow urine flow and drainage during treatment, and afterwards when flow can be inhibited by swelling or expansion of the prostate caused by thermal ablation or other prostate surgery. If not for inhibited urine flow caused by thermal ablation or prostate surgery, *Cioanta et al.*'s system would seem to serve no purpose.

Finally, the applicants respectfully submit that the markers shown in Fig. 5A of *Cioanta et al.* do not change the structure, purpose or function of *Cioanta et al.*'s balloons, stent or catheter in any pertinent manner, but may be applied simply "to block the transmission of X-ray [sic] for better contrast in images". See *Cioanta et al.* column 15, lines 7-9.

It is clear that the structure, function, and principle disclosed by *Cioanta et al.* is starkly different than the applicant's claimed invention.

For at least the foregoing reasons, the applicants submit that independent claims 1 and 45 are not anticipated by *Cionata et al.* and are in condition for allowance. Claims 2, 3, 5, 6-11, 17, 18, and 20 ultimately depend from claim 1. Claims 46-52, 58, 59, 61 and 64-65 ultimately depend from independent claim 45. Accordingly, the applicant submits that these dependent claims are also in condition for allowance.

CONCLUSION

The applicants submit that in addition to claims 21-44, claims 1-20 and claims 45-61 and

64-66 are in condition for allowance.

Each of the Examiner's rejections has been addressed or traversed. Accordingly, it is respectfully submitted that the application is in condition for allowance. Early and favorable action is respectfully requested.

If for any reason this Response is found to be incomplete, or if at any time it appears that a telephone conference with counsel would help advance prosecution, please telephone the undersigned or his associates, collect in Waltham, Massachusetts at (781) 890-5678.

Respectfully submitted,

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